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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/612,921
Filing Date: July 10, 2000
Appellant(s): SIMS, JOHN E.

Salvatore J. Arrigo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 02, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is agreed with.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Skolnick et al., 2000, TIBTECH, Vol. 18, pp. 34-39.

Bork et al., 1998, Current Opinion in Structural Biology, 8, pp.331-332.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

5. Claims 58-62 and 65-67 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is

insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. It is clear from the instant specification that the claimed novel nucleic acid molecule of SEQ ID NO: 3 encodes a polypeptides of SEQ ID NO: 4, designated "IL-1 delta" (bottom at page 5, continuing to page 6 of the instant specification). It is further disclosed that "[h]uman IL-1 delta polypeptide exhibited little identity with IL-1α, 29% identity with IL-1β, 50% identity with IL-1ra, little identity with IL-18, 31% identity with IL-1 epsilon, and 34% with IL-1 zeta" (page 9, lines 23-26). Therefore, based on the structural similarities to the mature forms of the other human IL-1 family members, it has been asserted that the novel polypeptides of SEQ ID NO: 4, encoded by the claimed nucleic acid of SEQ ID NO: 3 is a new member of IL-1 family of cytokines. The biological functions of IL-1 cytokines are diverse and include activation of vascular endothelial cells and lymphocytes, certain immune and inflammatory reactions, as well as regulation of cell cycle (see pages 2-3 of the instant specification, for example). Thus, based on limited structural similarity to IL-1 cytokines, it has been suggested that the NHP of the instant invention would also possess similar biological activity. Numerous publications exist on a topic of predicting protein functions from structural similarities or homology to the known proteins. It is well described in the art that amino acid structure cannot necessarily predict the function of the protein: "Knowing the protein structure by itself is insufficient to annotate a number of functional classes and is also insufficient for annotating the specific details of protein function" (see Skolnick et al., Box 2 on page 36 and the whole paper). Moreover, "Structural similarity does not necessarily mean a

common evolutionary origin and homologous sequences may evolve into different folds (according to current classification schemes) (See Bork et al., Current Opinion in structural Biology, 1998, 8, page 332, first column, second paragraph). Thus, according to the state of the art, functional characteristics of a protein cannot be unequivocally extrapolated from its structural characteristics. Based on the information provided in the instant specification, as filed, one skilled in the art would reasonably conclude that the instant IL-1 delta probably belongs to IL-1 group of cytokines or at least is evolutionary related to the group. However, the artisan would have to perform significant amount of further research to determine which function is attributed to the instant novel IL-1 delta polypeptide.

In the absence of knowledge of the biological significance of this specific IL-1 delta protein or encoding nucleic acid molecule, there is no immediately obvious patentable use for the claimed IL-1 delta nucleic acids. According to the specification of the instant application IL-1 delta " nucleic acids [could be used] to identify genes associated with certain diseases, syndromes, or other human conditions associated with human chromosome 2" (page 6, lines 14-19 of the instant specification). However, the instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant nucleic acid or encoded protein are associated with any disease or disorder. To employ the IL-1 delta DNA "as probes to identify nucleic acid encoding proteins having IL-1 delta activity" or in future methods of gene therapy (page 36, lines 4-13) is not a "real world" utility because it would eventually relate to a protein for which no biological function is known. The instant application also fails to demonstrate use of the protein as a marker for any disease or condition, including "glaucoma,

ectodermal dysplasia, insulin-dependent diabetes mellitus, wrinkly skin syndrome, T-cell leukemia/lymphoma, and tibial muscular dystrophy" (page 37, lines 25-27).

Thus, to employ IL-1 delta nucleic acids of the instant invention in any of the disclosed methods, would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the nucleic acid or the encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

Claims 58-62 and 65-67 are rejected under 35 U.S.C. 112, first paragraph because the instant specification does not disclose specific, substantial and credible utility of the claimed isolated nucleic acids, then one skilled in the art clearly would not know how to use the claimed invention.

Further, claims 60-61 and 65-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 60-61 are directed to isolated nucleic acid molecules comprising at least 30 or 60 contiguous nucleotides of SEQ ID NO: 3. Claims 65-67 are directed to isolated nucleic acid molecules having at least 95%, 98% or 99% sequence identity with a sequence of SEQ ID NO: 3. The claims do not require that the claimed polynucleotides possess any particular biological

activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by sequence identity. However, the instant specification fails to describe the entire genus of nucleic acids, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 4. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO: 3. The claims are drawn to nucleic acids that are fragments of a nucleic acid of SEQ ID NO: 3 or have at least 95%, 98% or 99% sequence identity with a sequence of SEQ ID NO: 3. Thus, the claims are not limited to a polynucleotide with a specific nucleic acid sequence. The claims only require the claimed polynucleotides to share some degree of structural similarity to the isolated nucleic acid of SEQ ID NO: 3. The specification only describes an isolated nucleic acid having the sequence of SEQ ID NO: 3 and fails to teach or describe any other nucleic acid which lacks the sequence of SEQ ID NO: 3 and has the activities possessed by IL-1 delta of the instant invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of the length of the fragment or percent identity.

There is not even identification of any particular portion of the structure that must be conserved. The specification does not provide a complete structure of those fragments of a nucleic acid of SEQ ID NO: 3 or nucleic acid molecules that have at least 95%, 98% or 99% sequence identity with a sequence of SEQ ID NO: 3 and fails to provide a representative number of species for the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid molecule comprising the nucleic acid sequence set forth in SEQ ID NO: 3, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

(11) Response to Argument

1. Beginning at page 7, section A of the Brief, Appellant summarizes number of utilities for human IL-1 delta nucleic acid molecules. Appellant submits that "[o]ne of those utilities is the use of the claimed nucleic acid molecules as a genetic marker to distinguish conditions in which the human IL-1 delta gene on the proximal long arm of chromosome 2 is rearranged or deleted" (bottom at page 7). Appellant refers to the instant specification at page 37, lines 24-37, to support the assertion of specific, substantial and credible utility of the claimed nucleic acid of SEQ ID NO: 3 as being a marker for 2q11-12 region of chromosome 2, which at the time of invention, is disclosed to be linked to "glaucoma, ectodermal dysplasia, insulin-dependent diabetes mellitus, wrinkly skin syndrome, T-cell leukemia/lymphoma, and tibial muscular dystrophy". These arguments have been fully considered but are not deemed persuasive for the following reasons.

The Examiner maintains the position that the employment of DNA sequences of the instant invention as chromosome markers does not constitute a specific and substantial credible utility. One skilled in the art readily understands that DNA encoding IL-1 delta is not the only DNA that can be used to specifically identify chromosome 2. Therefore, to accept Applicant's arguments that a nucleic acid encoding a protein of human origin is useful as a chromosome marker would be comparable to conceding that any object of fixed mass has *prima facie* utility as

a weight standard, irrespective of any other properties possessed by that object. One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. One could further extrapolate upon this premise by asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process, which measures that parameter. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound, which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well-known process of combustion for purposes of lighting and/ or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

To grant Appellant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise

delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the protein encoded thereby can be employed as a chromosome marker is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a fuel source.

At page 9, section 2 of the Brief, Appellant argues that "[t]he specificity of this utility [to specifically hybridize to a particular region in chromosome 2] arises from the specific location of the human IL-1 delta gene on the proximal long arm of chromosome 2" and refers to Declaration of Sims for support of these arguments. Applicant's arguments and The Declaration of Sims under 37 CFR 1.132 filed on December 19, 2003 have been fully considered but are not deemed to be sufficient or persuasive for the following reasons. The Examiner maintains the position that the fact the human IL-1 delta has a specific location on a specific chromosome does not constitute a specific and substantial utility. One skilled in the art readily understands that any naturally occurring DNA has a "specific location" on a specific corresponding chromosome. However, such specificity does not support a specific substantial utility of that DNA. To use the novel polynucleotides of the instant invention "to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted" (page 10, section 3 of the Brief) without knowledge of these conditions in view of the absence of information regarding a specific biological function of IL-1 delta or its specific association with a pathological condition would be equivalent to using

them as an object of future research to establish the utility of the IL-1 delta. It is a matter of law that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. At the time the instant invention was made, the only information available regarding "Identifying Associated Disease" (page 37, line 23 of the instant specification) by using DNA of SEQ ID NO: 3 was an assertion that because SEQ ID NO: 3 maps to the 2q11-12 region of chromosome 2, and because human chromosome 2 has been reported to be associated with a number of unrelated pathological syndromes and conditions such as "glaucoma, ectodermal dysplasia, insulin-dependent diabetes mellitus, wrinkly skin syndrome, T-cell leukemia/lymphoma, and tibial muscular dystrophy" (page 37, 25-27), then nucleic acid molecule of SEQ ID NO: 3 is also associated with these conditions. However, the instant specification fails to provide any evidence or sound scientific reasoning to support a conclusion that this instant nucleic acid of SEQ ID NO: 3 is associate with a particular disease or condition, including any of the conditions potentially related to abnormalities within human chromosome 2. Therefore, based on the information provided in the instant disclosure, as filed, one would reasonably conclude that it would require significant further research to establish which one, if any, specific pathological condition can be identified using nucleic acid of SEQ ID NO: 3.

A specification can meet the legal requirements of utility and enablement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide, or a well-established utility for the claimed polynucleotide would be readily available to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed

polynucleotide is presented in a mutated form in colon cancer and in normal form in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed polynucleotide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern here. The instant specification discloses that the human IL-1 delta gene maps to chromosome region 2q11-12 and hypothesizes that the detection of claimed polynucleotides can be used for the diagnosis of physical abnormalities associated with rearrangements in that region. However, there is no disclosure of any particular disease or pathological condition, which are specifically associated with such rearrangement. Absent a disclosure of altered levels or forms of a gene in diseased state as compared with the corresponding normal, the instant claimed nucleic acid molecule of SEQ ID NO: 3 is not a disease marker.

At page 11 of the Brief, Appellant argues that the substantial utility of IL-1 delta nucleic acids is supported by objective evidence of record and refers to two publications, specifically Mu et al., 1984, and Glass et al., 1998, both originally presented with submission of the Declaration of Sims. It is noted that Appellant incorrectly indicated that article of Glass et al. was published in 1988, while the correct date of publication is April 1998, as evidenced by publication record of Journal of Medical Genetics, vol. 35, 1998. Thus, Glass et al. article cannot be relied upon in establishing state of the art at the time of the invention, as it is a post-filing reference. With regards to publication of Mu et al., 1984, which describes a patient with various abnormalities, such as mental retardation and physical defects, there appears to be no support for Appellant's statement that the use of the instant claimed nucleic acid of SEQ ID NO: 3 would provide benefit

from diagnosis "to identify the cause of the physical abnormalities exhibited by the patient [described by Mu et al.], and would rule out other causes of the abnormalities". On the contrary, because the specification, as filed, has not linked the claimed polynucleotide with any specific physical abnormality by showing its differential expression specifically associated with such abnormality, use of the claimed nucleic acid of SEQ ID NO: 3 to locate 2q11-12 region of human chromosome 2 would not make the polynucleotide of SEQ ID NO: 3 any more "specific" than virtually any other polynucleotide mapped to the same region.

Thus, one would reasonably conclude that determining the relationship between the claimed polynucleotides and any specific pathological codition, including "short statue, microcephaly, brachycephaly, depressed nasal bridge, prominent philtrum, condenital glaucoma, and mental retardation" (see abstract of the artcle by Mu et al.), would require significant further research. For example, if *in situ* hybridization using claimed SEQ ID NO: 3 reveals certain rearrangement with human chromosome 2, what would that mean to the skilled artisan? Is it a marker for microcephaly, depressed nasal bridge or mental retardation, or any other pathological condition from the list presented on page 37, lines 24-37 of the instant specification? One skilled in the art readily understands that although hybridization of the instant polynucleotides to 2q11-12 chromosome region in case of patients described in publications of Mu et al. could establish sequential aberrations, one clearly would not know how to interpret that data without first making a substantial research contribution in order to discover a clear correlation between a physical abnormality and a mutated form of IL-1 delta polynucleotide.

With regards to Appellant's arguments that "[n]o additional research is required to use the claimed nucleic acids" (middle at page 14 of the Brief), there appears to be no disagreement

that one skilled in the art could practice *in situ* hybridization using the instant claimed DNA, as well as any other DNA, without the need for any additional research. The skill in the art is high and *in situ* hybridization protocol itself is well known. The main issue at hand, however, remains that since the instant specification, as filed, does not disclose a specific condition or conditions associated with rearrangement or deletion of 2q11-12, hybridization of polynucleotides of SEQ ID NO: 3 to human chromosome 2 is not particularly useful. One skilled in the art readily understands that the instant nucleic acids could be used as a specific marker for a certain abnormality only if a specific mutation in 2q11-12 region is disclosed as being associated with that abnormality.

Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder, any information obtained from discovery of rearrangement or deletion of certain portion of human chromosome 2 would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696. Thus, it can be concluded that at the time of filing Applicant's invention was incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful, therefore, the instant rejection is maintained.

2. Because the instant specification does not disclose specific, substantial and credible utility of the claimed isolated nucleic acids for those reasons of record fully explained earlier,

then one skilled in the art clearly would not know how to use the claimed invention; therefore, the rejection of claims 58-62 and 65-67 under 35 U.S.C. 112, first paragraph is maintained.

3. At page 16 (section B) of the Brief, Appellant argues that "in conjunction with Appellant's disclosure of the DNA sequence of SEQ ID NO: 3, it is evident that Appellant had possession of the nucleic acids of claims 60 and 61 at the time that the application was filed". This argument has been fully considered but is not deemed to be persuasive for the following reasons.

The instant specification, as filed, describes only a nucleic acid of SEQ ID NO: 3. The specification fails to teach or describe any other nucleic acid which lacks the structure of nucleic acid of SEQ ID NO: 3 and has any relevance to IL-1 delta polypeptide, as being an asserted "genetic marker to distinguish conditions in which the human IL-1 delta gene on the proximal long arm of chromosome 2 is rearranged or deleted" (bottom at page 7 of the Brief). There is no disclosure of any particular complete or partial conserved structure, physical and/or chemical properties, functional characteristics, structure/function correlation, or other disclosed distinguishing feature, as well as a representative number of species for the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Appellant further argues that claims 65-67, as being dependent from claim 62, which is directed to an isolated nucleic acid molecule that hybridizes to SEQ ID NO: 3 under high stringency conditions, are adequately described in the instant specification and "it is clear that Appellant had possession of the nucleic acids of claims 65-[67] at the time the application was filed" (top at page 19 of the Brief). This argument has been fully considered but is not deemed to

be persuasive for the reasons of record as applied earlier to claims 60-61 in the instant Examiner's answer. Briefly, claims 65-57 are drawn to a genus of polynucleotides that is defined only by sequence identity. The specification only describes a nucleic acid of SEQ ID NO: 3 and fails to teach or describe any other nucleic acid which lacks the nucleic acid of SEQ ID NO: 3 and can be used as a genetic marker for certain pathological conditions. Furthermore, the instant specification fails to recite relevant identifying characteristics, such as physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize that Applicant was in possession of the claimed invention.

Therefore, for reasons set forth above, Appellants arguments have been fully and carefully considered, but are not considered sufficient to rebut the case of lack of utility, as well as lack of enablement and written description, and it is believed that the rejection should be sustained.

Respectfully submitted,

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September 27, 2004

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